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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,716	11/10/2003	John Allen Robinson	AM100401	5638
26691	7590	12/16/2004	EXAMINER	
POTTER ANDERSON & CORROON LLP ATTN: KATHLEEN W. GEIGER, ESQ. P.O. BOX 951 WILMINGTON, DE 19899-0951			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,716

Applicant(s)

ROBINSON ET AL.

Examiner

Anand U Desai, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 13-37 and 43-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20041013.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, drawn to claims 8-12, and 38-42, drawn to a polypeptide in the reply filed on November 5, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-7, 13-37, and 43-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 5, 2004.
3. The requirement is still deemed proper and is therefore made FINAL.
4. This application contains claims 1-7, 13-37, and 43-88 drawn to an invention nonelected without traverse filed on November 5, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

6. The priority date is November 12, 2002.

Information Disclosure Statement

7. The information disclosure statements (IDSs) submitted on October 13, 2004, and November 10, 2004 are being considered by the examiner.

Specification

8. The disclosure is objected to because of the following informalities:

9. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification. The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Suggest amending first paragraph of the specification to claim priority, such as "This application claims priority to U.S. provisional application serial no. 60/425,532, filed November 12, 2002."

10. There are typographical errors: On page 3, lines 13, and 33. There is a space missing between the colon and the number 2 on line 13, and the left parenthesis on line 33. On page 4, line 1 there is a space missing between the semi-colon and the left parenthesis.

11. On page 20, lines 20, 21, 24, and 25, what is the word, "etc" actually describing. Suggest clarifying or removing the word, "etc."

12. On page 21, line 17, the temperature is missing either Fahrenheit or Celsius?

Appropriate correction is required.

Claim Objections

13. Claim 8, 10, 12, 38, 39, and 42 are objected to because of the following informalities:

Claims 8, and 38 depend from a withdrawn claim 1.

Claims 10, and 12 have the abbreviation, PTH, suggest identifying PTH as parathyroid hormone in claim 10, for example, parathyroid hormone (PTH).

Claims 39, and 42 have the abbreviation, PAIGB, suggest identifying PAIGB as parathyroid responsive gene in claim 39.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Absent the word, “isolated” or “purified” prior to the word polypeptide, the polypeptide is directed to a product of nature.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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17. Claims 8-12, and 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
18. Claims 8, and 38 depend from withdrawn claim 1.
19. Claim 38 is drawn to a non-elected antibody composition. Suggest claiming the composition comprising the polypeptide of claim 8.
20. Claim 39 recites the limitation "said PAIGB" on the 1st line. There is insufficient antecedent basis for this limitation in the claim. Suggest, the PAIGB.
21. Claims 9-12, and 40-42 are rejected for depending on a rejected claim.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

23. Claims 8-12, and 38-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Afar, D. et al. WO 03/025138 A2 (Effective filing date=September 17, 2001). Afar, D. et al. disclose a polypeptide sequence that has 100 % identity to the currently claimed polypeptide identified as SEQ ID NO:4 (see WO 03/025138 A2, pg. 753, SEQ ID NO: 303, current application, claims 8-12, 38, and 42). A disclosed structural polypeptide will inherently dictate a function upon the

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disclosed polypeptide. Therefore, the peptide that has 100 % identity would be expected to possess the function currently being claimed (current application, claims 11, 40, and 41).

24. Claims 8-12, and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Tanner et al. US 2003/0119043 A1 (Effective filing date=November 9, 2001). Tanner et al. disclose a polypeptide sequence that has 100 % identity to the currently claimed polypeptide identified as SEQ ID NO:4 (see US 2003/0119043 A1, pg. 27-28, SEQ ID NO: 17, current application, claims 8-12, 38, and 42). A disclosed structural polypeptide will inherently dictate a function upon the disclosed polypeptide. Therefore, the peptide that has 100 % identity would be expected to possess the function currently being claimed (current application, claims 11, 40, and 41).

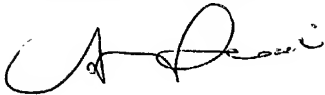
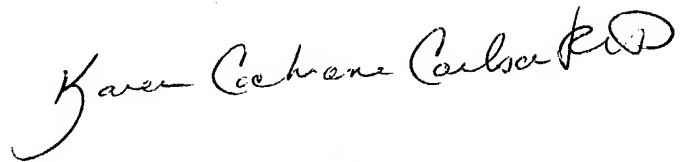
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 8, 2004

A handwritten signature in black ink, appearing to be 'A. De...'.A handwritten signature in black ink that reads 'Karen Cochrane Carlson' followed by a stylized monogram.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER